22 December 2023 21 December 2026 10558718

Original approval(s): ISO 13485 - 22 December 2017

LRQA

# **Certificate of Approval**

This is to certify that the Management System of:

## ITEST plus, s.r.o.

Kladská 1032/44c, Slezské Předměstí, 500 03 Hradec Králové, Czech Republic

has been approved by LRQA to the following standards:

### **CSN EN ISO 13485:2016**

Approval number(s): ISO 13485 - 0058035

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

### The scope of this approval is applicable to:

Performing of biological and microbiological testing for clients producing medical devices.

Sterility test, Determination of bacterial endotoxins, Determination of the population of microorganisms (bioburden), Determination of microbiological contamination of the environment (monitoring), Sampling of air - aeroscope, settle plates, sampling of surfaces swabs, contact plates.

Production and sale of diagnostic devices in vitro for microbiology.

Diagnostic discs, Carbohydrates diagnostic tablets, Antimycotic discs, latexaglutination diagnostic sets, other diagnostic discs, diagnostic sera for slide agglutination.

LRQA Group Limited, its affiliates and subsidiaries and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'LRQA'

**Paul Graaf** 

Area Operations Manager, Europe

Issued by: LRQA Limited



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Certificate identity number: 10558718

### **Certificate Schedule**

**Location** Activities

### ITEST plus, s.r.o.

Kladská 1032/44c, Slezské Předměstí, 500 03 Hradec Králové, Czech Republic

### **ČSN EN ISO 13485:2016**

Performing of biological and microbiological testing for clients producing medical devices.

Sterility test, Determination of bacterial endotoxins,

Determination of the population of micrographisms

Determination of the population of microorganisms (bioburden), Determination of microbiological contamination of the environment (monitoring), Sampling of air - aeroscope, settle plates, sampling of surfaces - swabs, contact plates.

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### ITEST plus, s.r.o.

Bílé Vchýnice 10 Vápno u Přelouče, Czech Republic

### **ČSN EN ISO 13485:2016**

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UKAS MANAGEMENT SYSTEMS

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